REMARKS/ARGUMENTS

This Amendment is being filed in response to the Final Office Action dated March 15, 2012. Reconsideration and allowance of the application in view of the remarks to follow are respectfully requested.

Claims 1-2 and 5-14 are pending in the Application. Claims 1, 5 and 11 are independent claims.

In the Final Office Action, claims 1, 2, 5-9 and 11-14 are rejected under 35 U.S.C. §102(b) over U.S. Patent Publication No. 2002/0013615 to Haim et al. ("Haim"). Claim 10 is rejected under 35 U.S.C. §103(a) over Haim in view of U.S. Patent Publication No. 2005/0220882 to Pritchard et al. ("Pritchard"). These rejections are respectfully traversed. It is respectfully submitted that the claims are allowable for at least the following reasons.

At page 7 of the Final Office Action, it is stated that the Applicant "has not explained why 'non-contact is not the same as detection of 'emergence of the tip of the catheter from the aneurysm.'" In response, the Applicants point out that Haim describes delivering or dispensing the drug not based upon the position of the catheter but instead upon inserting a needle into the tissue. Haim is silent on when and how the delivery of drug is terminated. In Haim once the needle 24 or 47 is inserted the position of the catheter plays no part in drug delivery or termination of such delivery.

The Final Office Action continues to rel on Haim, paragraphs [0105] – [0113] for showing the following recitation of claim 1:

> the monitor is
> configured to monitor the spatial position and/or orientation of the catheter based on the provided coordinates from the locator to detect

> emergence of the tip of the catheter from the aneurysm during the injection of the filling material into the aneurysm, and
>
> configured to stop the supply of the filling material in response to the detected emergence.

Haim paragraphs [0105] – [0113] take up at least two full columns or a full page of text. No indication is given in the rejection or the Response to Arguments as to exactly where in the referenced columns of text the relied upon language is found. Nevertheless, the Applicants once again analyzed the referenced paragraphs and provide the following analysis of the referenced paragraphs.

In paragraph [0105] Haim describes a sensors 36 as being "responsive to contact between distal end 22 and the heart wall so to assure proper contact between the catheter and the wall before extension of needle 24".

In paragraphs [0106] and [0107] Haim describes that "[a]fter the catheter is brought into engagement with a site in the heart wall where the drug is to be delivered, needle 47 is screwed into the wall by a corkscrew-like rotational movement" and that during insertion of the catheter into the heart, the needle 47 can be retracted into the catheter. That is done to ensure that the catheter remains attached while the drug is administered. Nothing within the four corners of Haim is disclosed regarding the needle disconnecting from the wall during the drug administration.

In paragraphs [0108] – [0110] Haim describes Figure 2 which shows a system 48 of FIG. 2 as having a catheter 20 connected to a console 50 having circuitry 52 coupled via wires 42 to elements of catheter 20 and a dispenser 54 having a reservoir into which the drug is filled, to dispense the drug through needle 24. In paragraph [0110] Haim describes

a preference for generating a viability map of the heart for identifying suitable candidate areas for drug administration and marking points on the map covering a candidate area at a desired density at which the drug is to be administered.

In paragraphs [0111]-[0113] Haim describes a FIG. 3 flow chart showing a method for concurrent viability mapping and drug administration. The flowchart performs six steps, before any drugs are injected. The catheter is inserted into the heart; navigated to a candidate area for drug administration; a position sensor 32 is then used to position the contact sensors 36 against the candidate area, the contact sensors 36 send signals to circuitry 52, which determines viability of the site or as in Haim "to ensure positive contact between the catheter's distal end and the endocardium". This step is alternatively described as follows:

> Alternatively or additionally, circuitry 52 may receive readings from the position sensor over several cardiac cycles, and to the extent that the position coordinates thus determined remain substantially constant (for any given phase of the cardiac cycle), it is assumed that distal end 22 is in positive contact with the endocardium.

It is respectfully submitted that Haim does not teach, disclose or suggest the needle disconnecting from the wall during the drug administration because the above discussed steps (see Figure 3 of Haim) are performed prior to the steps of moving to the next site if this one is not viable; moving to the next site if this one is not ischemic; and marking coordinates and viability status, which steps are described in paragraphs [0112]-[0113] a discussion of which follows.

Finally, in paragraph [0112]-[0113] Haim describes assessing the viability of the heart tissue at the location of the securely positioned distal end and generating motion

profile of the heart wall from sensor 32 to verify "that the heart tissue in a vicinity of the location of distal end 22 is ischemic but still viable before administering the drug at the location" and further that drug is not administered "at locations that do not meet the criteria of viability". Then, "Once it has been ascertained that distal end 22 of catheter 20 is firmly positioned at an ischemic site, needle 24 is extended out of sheath 26, as shown in FIG. 1B, and a dose of the drug is administered."

Accordingly, Haim does not address that the needle may inadvertently disconnect from the wall during the drug administration and thus fails to teach, disclose or suggest at least the above quoted element of claim 1. In particular, Haim fails to teach disclose, or suggest a device "configured ... to detect emergence of the tip of the catheter from the aneurysm during the injection of the filling material into the aneurysm, and configured to stop the supply of the filling material in response to the detected emergence".

In Response to Arguments the Final Office Action takes a position that "if the distal end or tip of the catheter has lost contact from the cardiac tissue where the aneurysm has occurred, drug supply is halted ([0028])." This position is respectfully refuted.

Haim in the paragraph [0028] states the following:

> Most preferably, the sensor also senses when the needle has been fully retracted into the catheter, to ensure that the catheter can be moved safely from one location to another. Preferably, drug administration is automatically disabled except when the catheter is in appropriate contact with a heart wall and the needle is projected to a desired length. Alternatively or additionally, a user of the apparatus is notified of the needle's position, with or without automatic disablement.

Thus, as previously discussed, drug administration is disabled when the needle is retracted, not when the tip of the catheter emerges "from the aneurysm during the injection", as for example recited in claim 1. Haim fails to address that the needle or the catheter with the needle may become inadvertently disconnected from the wall into which the needle is inserted while the drug is being delivered.

It is respectfully submitted that the claims are not anticipated or made obvious by the teachings of the presented prior art references. For example, Haim does not teach, disclose or suggest, amongst other patentable elements, (illustrative emphasis added) "a monitor connected to the active locator and the pump, wherein the monitor is configured to monitor the spatial position and/or orientation of the catheter based on the provided coordinates from the locator to detect emergence of the tip of the catheter from the aneurysm during the injection of the filling material into the aneurysm, and configured to stop the supply of the filling material in response to the detected emergence" as recited in claim 1, and as similarly recited in each of claims 5 and 11.

Pritchard is cited in rejecting the dependent claim and, as such, does not remedy the deficiencies of Haim.

Based on the foregoing, the Applicants respectfully submit that the independent claims are patentable and notice to this effect is earnestly solicited. The dependent claims respectively depend from one of the independent claims and accordingly are allowable for at least this reason as well as for the separately patentable elements contained in each of the claims. Accordingly, separate consideration of each of the dependent claims is respectfully requested.

In addition, Applicants deny any statement, position or averment of the Examiner that is not specifically addressed by the foregoing argument and response. Any rejections and/or points of argument not addressed would appear to be moot in view of the presented remarks. However, the Applicants reserve the right to submit further arguments in support of the above stated position, should that become necessary. No arguments are waived and none of the Examiner's statements are conceded.

Applicants have made a diligent and sincere effort to place this application in condition for immediate allowance and notice to this effect is earnestly solicited.

Respectfully submitted,

By _____

Gregory L. Thorne, Reg. 39,398
Attorney for Applicant(s)
May 14, 2012

THORNE & HALAJIAN, LLP
111 West Main Street
Bay Shore, NY 11706
Tel: (631) 665-5139
Fax: (631) 665-5101